18 July 2024
295–24

Call for submissions – Application A1289

Food derived from disease-resistant, low-reducing sugars and reduced browning potato line BG25

Food Standards Australia New Zealand (FSANZ) has assessed an application made by SPS International, Inc. to amend the Australia New Zealand Food Standards Code to permit the sale and use of food derived from a new food produced using gene technology: potato line BG25. This potato line has been genetically modified to have disease-resistance, low-reducing sugars and reduced browning. A draft food regulatory measure has been prepared. Pursuant to section 31 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist consideration of the draft food regulatory measure.

FSANZ is consulting on this application using the FSANZ Consultation Hub, built on the Citizen Space platform. Submissions on this application need to be made using the FSANZ Consultation Hub (https://consultations.foodstandards.gov.au/).

All submissions on applications and proposals will be published on the FSANZ Consultation Hub. We will not publish material that we accept as confidential. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1982*. Submissions will be published as soon as possible after the end of the submission period.

Under section 114 of the FSANZ Act, some information provided to FSANZ cannot be disclosed. More information about the disclosure of confidential commercial information is available on the FSANZ website at How to make a submission.

For information on how FSANZ manages personal information when you make a submission, see FSANZ's Privacy Policy.

FSANZ also accepts submissions in hard copy to our Australia and/or New Zealand offices. There is no need to send a hard copy of your submission if you have submitted it through the FSANZ Consultation Hub.

DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 29 August 2024

Submissions received after this date will not be considered unless an extension had been given before the closing date. Extensions will only be granted due to extraordinary circumstances during the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

Questions about making a submission or application and proposal processes can be sent to standards.management@foodstandards.gov.au.

Submissions in hard copy may be sent to the following addresses:

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Supporting document

The following document which informed the assessment of this application is available on the FSANZ website[1]:

SD1 Safety Assessment Report

[1] A1289 Food derived from disease-resistant, low-reducing sugars and reduced browning potato line BG25 | Food Standards Australia New Zealand

Executive summary

Food Standards Australia New Zealand (FSANZ) received an application from SPS International, Inc. to request a variation to Schedule 26 in the Australia New Zealand Food Standards Code (the Code) to permit the sale and use of food derived from a new food produced using gene technology (GM food): potato line BG25. Potato line BG25 has been genetically modified (GM) to have disease-resistance to late blight and *Potato virus Y*, as well as low-reducing sugars and reduced browning.

A safety assessment is a critical part of the assessment approval process for all GM food applications. The completed safety assessment for potato line BG25 is in Supporting Document 1. The assessment found no potential public health and safety concerns. Based on the data provided by the applicant and other information, food derived from potato line BG25 is considered to be as safe for human consumption as food derived from conventional non-GM potato varieties.

If approved, food derived from potato line BG25 may enter the Australian and New Zealand food supply as imported food products. These may include potato flour, potato starch, French fries and potato crisps.

If approved, existing labelling requirements for GM food would apply to food derived from potato line BG25 in accordance with the Code.

For reasons set out above and in the assessment summary, FSANZ has decided to prepare a draft variation to amend Schedule 26 of the Code to include a new item 5 (i) in the table to subsection S26—3(4) containing a reference to ‘disease resistant, low-reducing sugars and reduced browning potato line BG25’ to permit the sale and use of food derived from potato line BG25. If approved, the effect of the draft variation would be to permit the sale and use of food derived from this potato line in accordance with the Code.

FSANZ seeks submissions on the draft variation.

1 Introduction

1.1 The Applicant

SPS International, Inc. is a subsidiary of the United States of America (USA) food and agribusiness company J.R. Simplot Company, located in Boise Idaho, USA.

1.2 The Application

Application A1289 was submitted on 12 December 2023. It seeks an amendment to the Australia New Zealand Food Standards Code (the Code) to permit the sale and use of food derived from a new food produced using gene technology (GM food): potato line BG25. This potato line has been genetically modified to have disease-resistance to late blight and *Potato Virus Y*, as well as low-reducing sugars and reduced browning.

Resistance to late blight is conferred by the expression of three R-proteins: VNT1, AMR3 and BLB2, encoded by *Rpi-vnt1*, *Rpi-amr3* and *Rpi-blb2* genes respectively. They allow the plant to detect the presence of the infecting organism *Phytophthora infestans*, leading to the induction of the plant's immune response and elimination of the fungus.

BG25 contains novel double stranded RNA molecules that are expressed to trigger the RNA interference (RNAi) silencing pathway. Protection against PVY infection is achieved by silencing the PVY-CP gene encoding viral coat protein. Two endogenous genes are also silenced via RNAi: *Vlnv* encoding vacuolar invertase and *Ppo* encoding polyphenol oxidase. Silencing of *Vlnv* and *Ppo* genes results in lower reducing sugars and reduced browning, respectively.

BG25 also contains the modified acetolactate synthase (*StmAls*) gene from *S. tuberosum* that confers tolerance to imidazolinone herbicides. Imidazolinone tolerance was only used for selection of putative transformants during the transformation stage. The applicant has advised that herbicide tolerance is not a commercial trait in BG25.

The applicant has stated it does not currently intend to import food derived from potato line BG25 into Australia and New Zealand, but the primary aim of its application is to protect international trade. If approved, food derived from potato line BG25 may enter the Australian and New Zealand food supply as imported food products e.g. French fries, potato crisps, potato flour or potato starch.

1.2.1 Safety assessment sharing with Health Canada

This is the third GM application assessed under the joint safety assessment sharing arrangement with Health Canada.

Extensive work undertaken in the early stages of the collaboration confirmed the compatibility of FSANZ's and Health Canada's safety assessment approaches, both in terms of how safety assessments are conducted and the conclusions that are reached. Both agencies also adhere to internationally agreed principles and guidelines for the conduct of GM food safety assessment developed by the Codex *Ad Hoc* Intergovernmental Task Force on Foods derived from Biotechnology (Codex, 2009). This provides a strong basis for safety assessment sharing between the two agencies.

The goal of safety assessment sharing is to establish a system where a safety assessment is jointly prepared that meets the separate requirements of both agencies with each undertaking their own separate and independent assessments.

For potato line BG25 (the current application), the joint food safety assessment was initially prepared by FSANZ (SD1) and then provided to Health Canada for review and use as part of Health Canada's separate and independent approval processes.

1.3 The current standard

Pre-market approval

Standard 1.1.1 of the Code provides that, unless expressly permitted by the Code, a food for sale cannot be, or have as an ingredient or component, a GM food.[2] Standard 1.1.2 defines what is a 'food produced using gene technology' (referred to generally as a GM food in this report) for this purpose.[3]

The above in effect requires pre-market approval of a GM food before it can enter the Australian and New Zealand food supply. GM foods are only approved after a comprehensive pre-market safety assessment.

Standard 1.5.2 sets out the permission and conditions for sale of a food that is, or has as an ingredient, a GM food. Permitted GM foods are listed in Schedule 26 of the Code. Standard 1.5.2 also provides a GM food that is permitted for use as a food additive by Standard 1.3.1 or as a processing aid by Standard 1.3.3 is also a permitted GM food for the purposes of Standard 1.5.2.

Labelling

Standard 1.1.1 requires that food for sale must comply with all relevant labelling requirements imposed by the Code for that food.

Section 1.5.2—4 requires a food for sale that consists of, or has as an ingredient, a food that is a *genetically modified food* to be labelled as 'genetically modified'.[4] A genetically modified food is a GM food that:

- contains novel DNA or novel protein; or
- is listed in subsections S26—3(2), (2A) and (3) (i.e. regardless of the presence of novel DNA or novel protein in the foods). The foods listed in these subsections are considered to have an altered characteristic, such as an altered composition or nutritional profile, when compared to the existing counterpart food that is not produced using gene technology.

Section 1.5.2—4 also provides that its labelling requirement does not apply if the genetically modified food:

- has been highly refined (other than food that has an altered characteristic), where the effect of the refining process is to remove novel DNA or novel protein;
- is a substance used as a processing aid or a food additive and no novel DNA or novel protein from the substance remains present in the food for sale;
- is a flavouring substance present in the food in a concentration of no more than 1 g/kg (0.1%); or
- is unintentionally present in the food in an amount of no more than 10 g/kg (or 1%) of each ingredient; or

[2] See paragraphs 1.1.1—10(5)(c) and 1.1.1—10(6)(g)
[3] See definition in subsection 1.1.2—2(3).
[4] Subsection 1.5.2—4(5) defines genetically modified food to mean 'a *food produced using gene technology that
a) contains novel DNA or novel protein; or
b) is listed in Section S26—3 as subject to the condition that its labelling must comply with this section' (that being section 1.5.2—4).

- is intended for immediate consumption and is prepared and sold from food premises and vending vehicles, including restaurants, take away outlets, caterers or self-catering institutions.

The labelling requirements imposed by section 1.5.2—4 apply to the following in accordance with Standard 1.2.1:

- a food for retail sale. In the case where a food for retail sale is not required by the Code to bear a label and is not in a package, subsections 1.2.1—9(2) and (3) require labelling information in section 1.5.2—4 to accompany the food or be displayed in connection with the display of the food; or
- a food sold to a caterer. In the case where a food sold to a caterer is not required by the Code to bear a label, section 1.2.1—13 and paragraph 1.2.1—15(f) require information in section 1.5.2—4 to be provided to the caterer with the food.

1.4 Reasons for accepting application

The application was accepted for assessment because:

- it complied with the procedural requirements under subsection 22(2) of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act)
- it related to a matter that warranted the variation of a food regulatory measure
- it was not so similar to a previous application for the variation of a food regulatory measure that it ought to be rejected.

1.5 Procedure for assessment

The application is being assessed under the General Procedure.

2 Summary of the assessment

2.1 Safety assessment

The safety assessment of potato line BG25 is provided in Supporting Document 1 (SD1) and included the following key elements:

- a characterisation of the transferred genetic material, its origin, function and stability in the potato genome
- characterisation of novel nucleic acids and protein in the whole food
- detailed compositional analyses
- evaluation of intended and unintended changes
- assessment of the potential for any newly expressed protein to be either allergenic or toxic in humans.

In conducting the safety assessment, FSANZ considered information from a variety of sources including, but not limited to, a data package provided by the applicant (application and study reports), the scientific literature and previous applications.

The assessment of potato line BG25 was restricted to human food safety and nutritional issues. This assessment therefore does not address any risks to the environment that may occur as the result of growing potato line BG25, or any risks to animals that may consume feed derived from potato line BG25. Permission to cultivate potato line BG25 in or to import viable tubers into Australia or New Zealand would require separate regulatory assessment

and approval by the Gene Technology Regulator (GTR)[5] in Australia and by the Environmental Protection Authority (EPA)[6] in New Zealand.

No potential public health and safety concerns have been identified.

Based on the data provided in the present application and other available information, food derived from potato line BG25 is considered to be as safe for human consumption as food derived from conventional non-GM potato varieties.

2.2 Risk management

The risk management options available to FSANZ after assessment were to either:

- reject the application, or
- prepare a draft variation of the Code.

For the reasons listed in this report, FSANZ decided to prepare a draft variation to the Code to permit the sale and use of food derived from potato line BG25. If approved, the effect of the draft variation would be to permit the sale and use of food derived from this potato line in accordance with the Code.

2.2.1 Regulatory approval

Potato line BG25 is a GM food for Code purposes as it is derived from 'an organism which has been modified by gene technology'. FSANZ is proposing to list potato line BG25 in the table to subsection S26—3(4). If approved, the proposed amendment would provide permission for the sale and use of food derived from potato line BG25 as a GM food in accordance with the Code.

2.2.2 Labelling

2.2.2.1 Requirement to be labelled as 'genetically modified'

In accordance with the labelling provisions in Standard 1.5.2 (see section 1.3 of this report), food for sale derived from a GM food such as potato line BG25 would be required to be labelled as 'genetically modified' if, among other things, the GM food:

- contains novel DNA or novel protein; or
- is listed in subsection S26—3(2), S26—3(2A) or S26—3(3) of Schedule 26 as being subject to the condition that the labelling must comply with section 1.5.2—4 of Standard 1.5.2 (such food has altered characteristics).

FSANZ has determined that food derived from potato line BG25 does not have altered characteristics (see section 5.3 of SD1).

Refined products from potato line BG25, such as alcohol, are unlikely to contain any novel DNA or novel protein and would be unlikely to require labelling as 'genetically modified'.

Cooked and processed products derived from potato line BG25 (e.g. French fries, potato flour, potato crisps, potato starch) would likely contain novel DNA or novel protein, and if so, would require labelling as 'genetically modified'.

Should approval be granted in the future for the cultivation and/or importation of potato line

[5] The Office of the Gene Technology Regulator (OGTR) provides administrative support to the Gene Technology Regulator in the performance of functions under the Gene Technology Act 2000.
[6] The EPA implements and enforces the Hazardous Substances and New Organisms (HSNO) Act 1996.

BG25, the sale of unpackaged raw potatoes (e.g. sold loose from a bulk bin) would trigger the requirement for the 'genetically modified' statement to accompany the food or be displayed in connection with the display of the food.

Section 1.5.2—4 of the Code generally requires a food for sale that consists of a GM food or has a GM food as an ingredient to be labelled as 'genetically modified', unless one of the exemptions listed in subsection 1.5.2—4(1) apply. Where required, the label statement 'genetically modified' must be made in conjunction with the name of the GM food (subsection 1.5.2—4(2)). If the GM food is present in the food for sale as an ingredient, food additive or processing aid, then the required statement may be included in the statement of ingredients (subsection 1.5.2—4(3)).

2.2.3 Detection methodology

An Expert Advisory Group (EAG) comprising laboratory personnel and representatives of Australian and New Zealand jurisdictions was formed by the Food Regulation Standing Committee's Implementation Sub-Committee[7] to identify and evaluate appropriate methods of analysis associated with all applications to FSANZ, including those applications for food produced using gene technology (GM applications).

The EAG indicated that for GM applications, the full DNA sequence of the insert and adjacent genomic DNA are sufficient data to be provided for analytical purposes. Using this information, any DNA analytical laboratory would have the capability to develop a PCR[8]-based detection method. This sequence information was supplied by the applicant for A1289.

2.3 Risk communication

2.3.1 Consultation

Consultation is a key part of FSANZ's standards development process.

FSANZ developed and applied a standard communication strategy to this application. All calls for submissions are notified via the FSANZ Notification Circular, media release, FSANZ's social media channels and Food Standards News. Subscribers and interested parties are also notified about the availability of reports for public comment.

The process by which FSANZ approaches standards development matters is open, accountable, consultative and transparent. Public submissions are called to obtain the views of interested parties on the draft variation.

The draft variation will be considered for approval by the FSANZ Board taking into account all public comments received on this call for submissions.

The applicant and individuals and organisations that make submissions on this application will be notified at each stage of the assessment.

2.3.2 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obliged to notify WTO members where proposed mandatory regulatory measures are not substantially the same as existing international standards and the proposed measure may have a significant effect on trade.

There are no relevant international standards and amending the Code to permit food derived

[7] Now known as the Implementation Subcommittee for Food Regulation.
[8] Polymerase Chain Reaction.

from potato line BG25 is unlikely to have a significant effect on international trade. Therefore, a notification to the WTO under Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade or Application of Sanitary and Phytosanitary Measures Agreement was not considered necessary.

2.4 FSANZ Act assessment requirements

When assessing this application and the subsequent development of a food regulatory measure, FSANZ has had regard to the following matters in section 29 of the FSANZ Act:

2.4.1 Section 29

2.4.1.1 Consideration of costs and benefits

FSANZ has considered the costs and benefits of permitting the sale and use of food derived from a new food produced using potato line BG25, as required by the FSANZ Act. A Regulatory Impact Statement (RIS) has not been prepared.

FSANZ expects that the benefits of the permission will likely exceed the costs. This assessment is discussed in more detail below.

Changes to Regulatory Impact Statement requirements

Impact analysis arrangements are no longer required to be finalised with the Office of Impact Analysis (OIA) as a result of changes made to the impact analysis requirements[9]. These changes mean FSANZ is responsible for deciding whether a RIS should be developed for proposals to amend the Code.

Prior to these changes, the OIA advised FSANZ that a RIS was not required for applications relating to GM food. This is because applications relating to permitting the use of GM food that have been determined to be safe are considered to be minor and deregulatory in nature, as their use will be voluntary if the draft variation concerned is approved.

On this basis, FSANZ's assessment is that a RIS is not required for this application.

Consideration of costs and benefits under the FSANZ Act

FSANZ has given consideration to the costs and benefits that may arise from the proposed measure for the purposes of meeting FSANZ Act considerations.

The FSANZ Act requires FSANZ to have regard to whether costs that would arise from the proposed measure outweigh the direct and indirect benefits to the community, government or industry that would arise from the proposed measure (paragraph 29(2)(a)).

The purpose of this consideration is to determine if the community, government and industry as a whole is likely to benefit, on balance, from a move from the status quo, where status quo is rejecting the application.

This analysis considers permitting the sale and use of food derived from a new food produced using gene technology: potato line BG25.

The consideration of the costs and benefits in this section is not intended to be an exhaustive, quantitative economic analysis of the proposed measures and, in fact, most of

[9] Regulatory Impact Analysis Guide for Ministers' Meetings and National Standard Setting Bodies | The Office of Impact Analysis (pmc.gov.au)

the effects that were considered cannot easily be assigned a dollar value.

Rather, the assessment seeks to highlight the potential positives and negatives of moving away from the status quo by approving the variation to the Code proposed by the application.

The benefits and costs of permitting potato line BG25

The food industry may benefit from this application being approved.

Potato line BG25 is developed to have a number of advantages that may increase productivity for growers, including protection against late blight infection, protection against PVY infection and reduced blackspot. The potato line also has lower reducing sugars (fructose and glucose) which may increase demand relative to other potato varieties. The permission is voluntary, therefore manufacturers will only use the potato line where a commercial net benefit exists for them.

The magnitude of these benefits has not been assessed.

Any benefits experienced by growers may flow through to other elements of the food supply chain that use potato line BG25, for example exporters, fresh food retailers or manufacturers of processed food.

From a regulatory impact perspective, FSANZ does not anticipate the permission results in cost impacts for industry. This is because use of the permission is voluntary, businesses will only engage with foods derived from potato line BG25 where they believe a net benefit exists for them. These businesses may experience costs related to the permission, but only where they have chosen to use the permission[10].

Any cost savings experienced by any part of the food industry may be passed onto consumers.

Consumers may also benefit from greater choice in potato varieties. As noted above, potato line BG25 has lower fructose and glucose relative to the Russet Burbank potato variety it is based on, which some consumers may value.

There are not expected to be any significant costs to consumers, because:

- FSANZ has assessed foods derived from potato line BG25 as safe to consume
- they will have an informed choice as all products containing GM food are required to be labelled.

There are not expected to be any significant costs or impacts for governments. There may be small and likely inconsequential costs of monitoring an extra GM food ingredient for regulators to ensure compliance with labelling requirements.

Conclusions of consideration of costs and benefits

FSANZ considers it likely that the direct and indirect benefits of permitting the sale and use of food derived from a new food produced using potato line BG25 outweigh the costs.

FSANZ will consider all information received from the call for submissions, and update the assessment of the costs and benefits if required. This may result in FSANZ arriving at a different conclusion.

[10] For example, a processed food manufacturer may include potato derived from potato line BG25 in an existing product, replacing potato from another source. This manufacturer will be required to re-label this product to state it contains genetically modified ingredients. While updating the label is required by the Food Standards Code, it is not a regulatory cost because the manufacturer did not have to use potato derived from potato line BG25.

2.4.1.2 Other measures

There are no other measures (whether available to FSANZ or not) that would be more cost-effective than a food regulatory measure developed or varied as a result of the application.

2.4.1.3 Any relevant New Zealand standards

The relevant standards apply in both Australia and New Zealand. There are no relevant New Zealand only Standards.

2.4.1.4 Any other relevant matters

The applicant has submitted applications for regulatory approval of potato line BG25 to other countries, as listed in Table 1.

Cultivation in Australia or New Zealand would require independent assessment and approval by the GTR in Australia and EPA in New Zealand.

Table 1. List of countries to whom applications for regulatory approval of BG25 have been submitted

Country	Authority	Type of approval sought	Status
United States	United States Department of Agriculture (USDA)	Determination of nonregulated status	Approved
	Environmental Protection Agency (EPA)	Environmental release	Submitted
	Food and Drug Administration (FDA)	Food and feed	Submitted
Canada	Canadian Food Inspection Agency (CFIA)	Environmental release	Submitted
	Health Canada (HC)	Food	Submitted

Other relevant matters are considered below.

2.4.2. Subsection 18(1)

FSANZ has also considered the three objectives in subsection 18(1) of the FSANZ Act during the assessment.

2.4.2.1 Protection of public health and safety

FSANZ's assessment did not identify any public health and safety concerns with food derived from potato line BG25. Based on the best available scientific evidence, including detailed studies provided by the applicant, FSANZ's assessment is that food derived from potato line BG25 is as safe for human consumption as food derived from other conventional non-GM potato varieties.

2.4.2.2 The provision of adequate information relating to food to enable consumers to make informed choices

Existing labelling requirements for GM food will apply to food derived from potato line BG25 in accordance with the Code to enable informed consumer choice (see section 2.2.2).

2.4.2.3 The prevention of misleading or deceptive conduct

The provision of DNA sequence information by the applicant (as described in section 2.2.3) satisfies this objective.

2.4.3 Subsection 18(2) considerations

FSANZ has also had regard to:

- **the need for standards to be based on risk analysis using the best available scientific evidence**

FSANZ's approach to the safety assessment of all GM foods applies concepts and principles outlined in the Codex Principles for the Risk Analysis of Foods derived from Biotechnology (Codex, 2009). Based on these principles, the risk analysis undertaken by FSANZ for potato line BG25 used the best scientific evidence available. The applicant submitted a comprehensive dossier of quality-assured raw experimental data. In addition to the information supplied by the applicant, other available resource material including published scientific literature and general technical information was used by FSANZ in the safety assessment.

- **the promotion of consistency between domestic and international food standards**

This is not a consideration as there are no relevant international standards.

- **the desirability of an efficient and internationally competitive food industry**

The inclusion of GM foods in the food supply, providing there are no safety concerns, allows for innovation by developers and a widening of the technological base for producing foods. Potato line BG25 is a new food crop with resistance to the late blight fungal disease and *Potato Virus Y*, potentially enabling farmers to use less fungicide and pesticide to ensure optimal crop yields. Furthermore, the BG25 is designed to have lower reducing sugars and reduced browning in raw potatoes. The applicant has indicated that reduced browning can reduce wastage during storage and processing of potatoes, and low reducing sugars may improve storage which will potentially benefit consumers.

- **the promotion of fair trading in food**

Issues related to consumer information and safety are considered in sections 2.2 and 2.3 above.

- **any written policy guidelines formulated by the Food Ministers' Meeting**

No specific policy guidelines have been developed.

3 Draft variation

The draft variation to the Code is at Attachment A and is intended to take effect on the date of gazettal.

A draft explanatory statement is at Attachment B. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislation.

4 References

Codex (2009) Principles for the risk analysis of foods derived from modern biotechnology. CAC/GL 44-2003. Codex Alimentarius Commission, Rome. http://www.fao.org/3/a1554e/a1554e00.htm

Attachments

A. Draft variation to the Australia New Zealand Food Standards Code
B. Draft Explanatory Statement

Attachment A – Draft variation to the Australia New Zealand Food Standards Code

Food Standards (Application A1289 – Food derived from disease-resistant, low-reducing sugars and reduced browning potato line BG25) Variation

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The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The variation commences on the date specified in clause 3 of the variation.

Dated [To be completed by the delegate]

Christel Leemhuis
Delegate of the Board of Food Standards Australia New Zealand

Note:

This variation will be published in the Commonwealth of Australia Gazette No. FSC XX on XX Month 20XX. This means that this date is the gazettal date for the purposes of clause 3 of the variation.

1 Name

This instrument is the *Food Standards (Application A1289 – Food derived from disease-resistant, low-reducing sugars and reduced browning potato line BG25) Variation*.

2 Variation to a Standard in the *Australia New Zealand Food Standards Code*

The Schedule varies a Standard in the *Australia New Zealand Food Standards Code*.

3 Commencement

The variation commences on the date of gazettal.

Schedule

Schedule 26—Food produced using gene technology

[1] Subsection S26—3(4) (table item 5, column headed "*Food derived from*:")

Insert:

(i) disease-resistant, low-reducing sugars and reduced browning potato line BG25

Attachment B – Draft Explanatory Statement

DRAFT EXPLANATORY STATEMENT

Food Standards Australia New Zealand Act 1991

Food Standards (Application A1289 – Food derived from disease-resistant, low-reducing sugars and reduced browning potato line BG25) Variation

1. Authority

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).

Division 1 of Part 3 of the FSANZ Act specifies that the Authority may accept applications for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering an application for the development or variation of food regulatory measures.

The Authority accepted Application A1289 which seeks to amend the Code to permit the sale and use of food derived from a new food produced using gene technology (GM food) – potato line BG25. Potato line BG25 has been genetically modified to have disease-resistance, low-reducing sugars and reduced browning. The Authority considered the Application in accordance with Division 1 of Part 3 and has prepared a draft variation - the *Food Standards (Application A1289 – Food derived from disease-resistant, low-reducing sugars and reduced browning potato line BG25) Variation*.

2. Variation will be a legislative instrument

If approved, the draft variation would be a legislative instrument for the purposes of the *Legislation Act 2003* (see section 94 of the FSANZ Act) and be publicly available on the Federal Register of Legislation (www.legislation.gov.au).

If approved, this instrument would not be subject to the disallowance or sunsetting provisions of the *Legislation Act 2003.* Subsections 44(1) and 54(1) of that Act provide that a legislative instrument is not disallowable or subject to sunsetting if the enabling legislation for the instrument (in this case, the FSANZ Act): (a) facilitates the establishment or operation of an intergovernmental scheme involving the Commonwealth and one or more States; and (b) authorises the instrument to be made for the purposes of the scheme. Regulation 11 of the *Legislation (Exemptions and other Matters) Regulation 2015* also exempts from sunsetting legislative instruments a primary purpose of which is to give effect to an international obligation of Australia.

The FSANZ Act gives effect to an intergovernmental agreement (the Food Regulation Agreement) and facilitates the establishment or operation of an intergovernmental scheme (national uniform food regulation). That Act also gives effect to Australia's obligations under an international agreement between Australia and New Zealand. For these purposes, the Act establishes the Authority to develop food standards for consideration and endorsement by the Food Ministers Meeting (FMM). The FMM is established under the Food Regulation Agreement and the international agreement between Australia and New Zealand, and consists of New Zealand, Commonwealth and State/Territory members. If endorsed by the FMM, the food standards on gazettal and registration are incorporated into and become part of Commonwealth, State and Territory and New Zealand food laws. These standards or instruments are then administered, applied and enforced by these jurisdictions' regulators as

part of those food laws.

3. Purpose

The Authority has prepared a draft variation amending the table to subsection S26—3(4) in Schedule 26 of the Code to permit the sale and use of food derived from potato line BG25, in accordance with the Code. Potato line BG25 has been genetically modified to have disease-resistance, low-reducing sugars and reduced browning.

4. Documents incorporated by reference

This draft variation does not incorporate any documents by reference.

5. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1289 will include one round of public consultation following an assessment and the preparation of a draft variation and associated assessment summary. A call for submissions (including the draft variation) will be open for a six-week period.

Changes have been made to the Impact Analysis requirements by the Office of Impact Analysis (OIA).[11] Impact analysis is no longer required to be finalised with the OIA. Prior to those changes, the OIA advised FSANZ that a Regulatory Impact Statement (RIS) was not required for applications relating to GM foods, updated OIA reference: **OIA23-06225**. This is because applications relating to permitting the use of GM foods that have been determined to be safe are considered to be minor and deregulatory in nature, as their use will be voluntary if the draft variation relating to the application is approved. Under the new approach, FSANZ's assessment is that a regulatory impact statement is not required for this application.

6. Statement of compatibility with human rights

If approved, this instrument would be exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 44 of the Legislation Act 2003.

7. Variation

Clause 1 of the draft variation provides that the name of the variation is the *Food Standards (Application A1289 – Food derived from disease-resistant, low-reducing sugars and reduced browning potato line BG25) Variation*.

Clause 2 of the draft variation provides that the Code is amended by the Schedule to the variation.

Clause 3 of the draft variation provides that the variation will commence on the date of gazettal of the instrument.

Item [1] of the Schedule to the draft variation would amend Schedule 26 by inserting, in alphabetical order, new paragraph '(i)' into the column headed '*Food derived from:*' for item 5 of the table to subsection S26—3(4) of the Code. Item 5 of this table is headed 'Potato'.

The new paragraph (i) refers to 'disease-resistant, low-reducing sugars and reduced

[11] Regulatory Impact Analysis Guide for Ministers' Meetings and National Standard Setting Bodies | The Office of Impact Analysis (pmc.gov.au)

browning potato line BG25’.

If approved, the draft variation would permit the sale and use of food derived from potato line BG25 in accordance with the Code.